Section 5 - 510(k) Summary or 510(k) Statement

APPLICANT:	Spectrum Spine IP Holdings, LLC Atlanta, GA
Contact Person:	Dr. James Robinson 3045 Paces Lake Court Atlanta, GA 30339 Tel: (404) 550-1335
Application Correspondent:	Ottie Pendleton, Spectrum Spine, LLC Tel: 404-372-0389 Email: ottie@spectrumspine.com
PROPOSED TRADE NAME:	SS Fenestrated Facet Screw System
PREPARATION DATE:	10/22/13
DEVICE CLASSIFICATION:	Unclassified
CLASSIFICATION NAME:	System, Facet Screw Spinal Device
PRODUCT CODE:	MRW
DEVICE DESCRIPTION:	The SS Fenestrated Facet Screw System (FFS) is a permanent implant device made from Cobalt Chrome Alloy Per ASTM 1537. It is to be implanted from the posterior approach. The device is provided in one diameter and multiple lengths to accommodate the various anatomy of the spine. The device is intended to provide mechanical support and stability to the implanted level until biologic fusion is achieved. The SS Fenestrated Facet Screw System is cannulated and fenestrated which allows it to be used as a delivery system for bone graft. The system is not to be used with bone cement.
INDICATIONS FOR USE:	The SS Fenestrated Facet Screw System (FFS) is indicated for the posterior surgical treatment at L1-S1 (inclusive) spinal levels for the following: Spondylolisthesis; Spondylolysis; Pseudarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability. The system is intended for use with only autogenous bone graft material.
MATERIALS:	Medical grade Cobalt Chrome Alloy.
PREDICATE DEVICES:	• Trans1 Facet Screw (K073515) • X-Spine Systems Zygafix Spinal Facet Screw System (K123932)
TECHNOLOGIC CHARACTERISTICS:	The fundamental scientific principles and technological characterlstics, including the intended use, general design, and sizes of the devices are the same as, or similar to, the predicate devices.
PERFORMANCE DATA:	Testing of the FFS to demonstrate substantial equivalence included static and dynamic 3-point bending, screw axial pullout, and torque to failure. The testing standards utilized were, ASTM F543-07 "Standard Specification and Test Methods for Metallic Medical Bone Screws", F2193-02, "Standard Specifications and Test

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Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System," and ASTM F1264-03 "Standard Specification and Test Methods for Intramedullary Fixation Devices."

SAFETY & EFFECTIVENESS:

The Spectrum Spine Fenestrated Facet Screw System (FFS) is substantially equivalent to the predicate device (K073515). The devices have the same "Indications for Use", are available by prescription only, and are provided non-sterile for single-use only. The device has fenestrations to allow for the optional packing of bone graft similar to the predicate (K123932). The FFS system differs from the predicates in that the FFS is made from Cobalt Chrome alloy while the predicates are made from Titanium alloy. This differences does not negatively impact the overall safety and effectiveness of the device. Therefore it can be concluded that the FFS is both a safe and effective device and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

October 28, 2013

Spectrum Spine, LLC
Mr. Ottie Pendleton
3045 Pacer Lake Court
Atlanta, Georgia 30339

Re: K132126
Trade/Device Name: Spectrum Spine (SS) Fenestrated Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: July 17, 2013
Received: August 1, 2013

Dear Mr. Pendleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510(k) Number: K132126

Device Name: Spectrum Spine Fenestrated Facet Screw System

The SS Fenestrated Facet Screw System (FFS) is indicated for the posterior surgical treatment at L1-S1 (inclusive) spinal levels for the following: Spondylolisthesis; Spondylolysis; Pseudarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability. The system is intended for use with only autogenous bone graft material.

Prescription Use ____X____ or Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132126